

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 2 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application. Please cancel claims 1-39, 41, 45, 47, 51, 56 and 70-73.

1-39. (Canceled)

40. (Currently amended) A method for therapeutic immunization of a mammal harboring a persistent protozoan *Trypanosoma* infection comprising;

administering to the infected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide;

wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and wherein administration of the vaccine is effective to eliminate the parasite from the mammal.

41. (Canceled)

42. (Currently amended) The method of claim [[41]] 40 wherein the protozoan *Trypanosoma* is *T. cruzi*.

43. (Original) The method of claim 40 wherein the vaccine stimulates a CD8⁺ T cell response.

44. (Previously presented) The method of claim 40 wherein the multicomponent vaccine

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 3 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

comprises a plurality of polynucleotides comprising a nucleotide coding region encoding an immunogenic polypeptide, and at least one polynucleotide comprising a nucleotide coding region encoding a cytokine.

45. (Canceled)

46. (Currently amended) A method for therapeutic immunization of mammal harboring a persistent protozoan *Trypanosoma* infection comprising:

administering to the infected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide;

wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and wherein administration of the vaccine is effective to prevent or delay chronic debilitating disease in the mammal.

47. (Canceled)

48. (Currently amended) The method of claim [[47]] 46 wherein the protozoan *Trypanosoma* is *T. cruzi*.

49. (Original) The method of claim 46 wherein the vaccine stimulates a CD8⁺ T cell response.

50. (Previously presented) The method of claim 46 wherein the multicomponent vaccine

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 4 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

comprises a plurality of polynucleotides comprising a nucleotide coding region encoding an immunogenic polypeptide and at least one polynucleotide comprising a nucleotide coding region encoding a cytokine.

51. (Canceled)

52. (Currently amended) A method for therapeutic immunization of a mammal harboring a persistent protozoan *Trypanosoma* infection comprising:

administering to the infected mammal a vaccine comprising at least one component selected from the group consisting of

- (a) an immunogenic polypeptide and
- (b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide,

wherein the vaccine stimulates an antibody response, a Th1-biased CD4⁺ T cell response and a CD8⁺ T cell response against the protozoan *Trypanosoma* upon administration to a mammal; wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and [[,]] wherein administration of the vaccine is effective to eliminate the parasite from the mammal.

53. (Currently amended) A method for therapeutic immunization of mammal harboring a persistent protozoan *Trypanosoma* infection comprising:

administering to the infected mammal a vaccine comprising at least one component selected from the group consisting of

- (a) an immunogenic polypeptide and
- (b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide.

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 5 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

wherein the vaccine stimulates an antibody response, a Th1-biased CD4⁺ T cell response and a CD8⁺ T cell response against the protozoan *Trypanosoma* upon administration to a mammal; wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and wherein administration of the vaccine is effective to prevent or delay chronic debilitating disease in the mammal.

54. (Currently amended) A method for prophylactic immunization of a mammal against an infectious protozoan *Trypanosoma* comprising:

administering to an uninfected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide;

wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and wherein administration of the vaccine is effective to prevent subsequent infection of the mammal by the protozoan *Trypanosoma*.

55. (Currently amended) A method for prophylactic immunization of a mammal against an infectious protozoan *Trypanosoma* comprising:

administering to an uninfected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide;

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 6 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

wherein the immunogenic polypeptide comprises a protozoan Trypanosoma polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; wherein administration of the vaccine is effective to prevent the development of chronic debilitating disease the mammal after subsequent infection by the protozoan Trypanosoma.

56. (Canceled)

57. (Currently amended) The method of claim [[56]] 55 wherein the protozoan Trypanosoma is *T. cruzi*.

58. (Original) The method of claim 55 wherein the vaccine stimulates a CD8⁺ T cell response.

59. (Previously presented) The method of claim 55 wherein the multicomponent vaccine comprises a plurality of polynucleotides comprising a nucleotide coding region encoding an immunogenic polypeptide and at least one polynucleotide comprising a nucleotide coding region encoding a cytokine.

60. (Previously presented) The method of claim 55 wherein the multicomponent vaccine comprises a plurality of immunogenic polypeptides wherein the immunogenic polypeptide comprises a membrane translocating sequence.

61. (Currently amended) A method for prophylactic immunization of a mammal against an infectious protozoan Trypanosoma comprising:
administering to an uninfected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 7 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide;

wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide ~~that is associated with a protozoan cell surface or secreted by a protozoan comprising a~~ glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; wherein administration of the vaccine is effective to prevent the death of the mammal after subsequent infection by the protozoan *Trypanosoma*.

62. (Currently amended) A method for prophylactic immunization of a mammal against an infectious protozoan *Trypanosoma* comprising;

administering to an uninfected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an immunogenic polypeptide;

wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide ~~that is associated with a protozoan cell surface or secreted by a protozoan comprising a~~ glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and wherein administration of the vaccine is effective to prevent subsequent infection of the mammal by the protozoan *Trypanosoma*.

63. (Currently amended) A method for prophylactic immunization of a mammal against an infectious protozoan *Trypanosoma* comprising;

administering to an uninfected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 8 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

immunogenic polypeptide;

wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and wherein administration of the vaccine is effective to prevent the development of chronic debilitating disease the mammal after subsequent infection by the protozoan *Trypanosoma*.

64. (Currently amended) A method for prophylactic immunization of a mammal against an infectious protozoan *Trypanosoma* comprising:

administering to an uninfected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an

immunogenic polypeptide;

wherein the immunogenic polypeptide comprises a protozoan *Trypanosoma* polypeptide that is associated with a protozoan cell surface or secreted by a protozoan comprising a glycosylphosphatidylinositol anchor attachment site, or an immunogenic fragment of said polypeptide; and wherein administration of the vaccine is effective to prevent the death of the mammal after subsequent infection by the protozoan *Trypanosoma*

65. (Previously presented) A method for therapeutic immunization of a mammal harboring a persistent *T. cruzi* infection comprising:

administering to the infected mammal a multicomponent vaccine comprising a plurality of components selected from the group consisting of

(a) an immunogenic *T. cruzi* polypeptide and

(b) a polynucleotide comprising a nucleotide coding region encoding an

immunogenic *T. cruzi* polypeptide,

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 9 of 15

Serial No.: 09/518,156

Confirmation No.: 4178

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

wherein administration of the vaccine is effective to prevent or delay chronic debilitating disease in the mammal.

66. (Previously presented) The method of claim 65 wherein the multicomponent vaccine comprises a plurality of polynucleotides comprising a nucleotide coding region encoding an immunogenic *T. cruzi* polypeptide and at least one polynucleotide comprising a nucleotide coding region encoding a cytokine.

67. (Original) The method of claim 65 wherein administration of the multicomponent vaccine stimulates an antibody response, a Th1-biased CD4⁺ T cell response and a CD8⁺ T cell response in the mammal.

68. (Previously presented) The method of claim 65 wherein the multicomponent vaccine comprises a plurality of immunogenic *T. cruzi* polypeptides, and wherein the immunogenic polypeptide comprises a membrane translocating sequence.

69. (Original) The method of claim 65 wherein the mammal is a dog, a cat, or a human.

70-73. (Canceled)